

Serial No.: 10/075,970

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REMARKSStatus of the Claims

Claims 1-3, 5-7 and 9-21 are pending herein. Claims 4, 8 and 22-45 have been cancelled without prejudice or disclaimer.

Claim Rejection under 35 U.S.C. 102(e)—Steinke

Claims 1-3, 5-7, 9, 10 and 14-21 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,623,521 to Steinke et al. (Steinke). This rejection is respectfully traversed.

For a reference to anticipate a claim it must disclose each and every element of the claim. See MPEP 2131 and cases cited therein. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (CCPA 1978).

For anticipation a reference "must sufficiently describe the claimed invention to have placed the public in possession of it." *Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659, 231 U.S.P.Q. 649, 653 (Fed. Cir. 1986).

The reference fails as an anticipation in light of the MPEP and legal precedent.

The concept of the present claims is the control of changes in rigidity of a medical device, e.g., a stent, so that the device becomes decreasingly rigid and increasingly biomechanically compatible with body tissues in contact with the device over a period of time. That concept can not be found in the Steinke reference. *Ex parte Rubin*, 5 U.S.P.Q. 2d, 1461 (BPAI 1987).

The concept of Steinke is a particular method of forming a stent from a plurality of flat sliding and locking elements. All of the claims and essentially the complete disclosure are drawn to the mechanical aspects of that concept.

The stents of Steinke are biodegradable. "Coatings" are disclosed in a single short paragraph at column 17, line 31, to line 37, referenced by the examiner on page 2 of the Office Action. There is no disclosure in Steinke of selection of that coating so that it will perform the function recited in the instant claims. That element of the invention claimed and the concept embodied in that invention is not found in that paragraph or elsewhere in the reference. Indeed, these coatings are *hydrogels*, which would not provide absolutely no control over the rate at

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which the inner core material becomes flexible upon contact with bodily fluids as claimed in claim 1. Thus there is no anticipation. See the cases cited above.

Present claim 1 recites the properties of the two components of the device, "core" and "covering material," that enable "controlled change in mechanical properties and biomechanical compatibility" to be realized. The examiner has considered those properties to be not a material limitation capable of distinguishing over the reference. That position taken by the examiner is erroneous both legally and factually.

From a legal standpoint, to find anticipation of claims, the prior art embodiments must possess the properties expressly recited in the claims under examination. Property limitations can and do serve to distinguish the claimed subject matter from other products. See, merely for example, *E. I. DuPont de Nemours & Co. v. Phillips Petroleum Co.* 349 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988). See also, *In re Metcalfe*, 410 F.2d 1378, 161 U.S.P.Q. 523, 793 (CCPA 1969). Also "adapted to" recited in the claim is a property, not an intended use. *In re Paulsen*, 30 F.3d 1475, 31 U.S.P.Q.2d 1671, 1673 (Fed. Cir. 1994), *In re Walles*, 366 F.2d 786, 151 U.S.P.Q. 185, 190 (CCPA 1966), *Ex parte Schundehutte*, 184 U.S.P.Q. 697 (BPAI 1974).

From a factual standpoint, at column 17, lines 31-37 of Steinke occurs the only disclosure of an *optional* coating over the core stent disclosed. There is no disclosure of the function of the coatings or their properties relative to the of the core material.

Even assuming for the sake of argument that the disclosure of Steinke could possibly be considered to *encompass* the structure of the present claims, a reference disclosure that encompasses claimed subject matter only broadly does not anticipate it. *In re Baird*, 16 F.3d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994).

Moreover, Steinke most certainly would *not* put "the public in possession" of the here claimed invention. *Paperless Accounting, Inc. v. Bay Area Rapid Transit System, supra*.

In this particular case, one would first have to choose the option of using a coating in the first place and then select both a core material and coating from the many disclosed to result in the device of the instant claims. Even if a coating material were described in Steinke that could somehow provide the claimed properties, the requirements for anticipation discussed above would not be satisfied.

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With regard to claim 5, there is no mention of hydrophobic surface erodable polymers as the covering material. (Indeed, the hydrogel materials described at col. 17, lines 30-37 of Steinke are the antithesis of hydrophobic polymers.)

With regard to claim 7, there is no mention of shape memory biodegradable polymers as the covering material.

These constitute other elements lacking in Steinke to satisfy the requirements for anticipation discussed above.

Reconsideration and withdrawal of the above rejection are therefore requested.

Claim Rejection under 35 U.S.C. 103(a)—Steinke

Claims 11-13 have been rejected under 35 U.S.C. 103(a) as being obvious over the disclosure of Steinke. This rejection is respectfully traversed.

The examiner's conclusion of obviousness is based on the unsupported statement that "it is well known in the art" to produce stents from the types of material recited in claims 11-13. Without evidence, that type of conclusion is insufficient support for a *prima facie* case of obviousness. The requirements for making out a *prima facie* case of obviousness are set forth in MPEP 706.02(j). The examiner has failed to meet those requirements. The examiner has yet to provide an explanation based on logic and sound scientific reasoning, see *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (BPAI 1993). The more fundamental defects of the Steinke reference to support any rejection are pointed out above and need not be repeated here.

CONCLUSION

Applicant submits all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

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If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

Respectfully submitted,

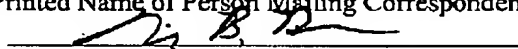
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